

ATTACHMENT A

CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND LANKENAU HOSPITAL

PREAMBLE

Lankenau Hospital ("Hospital") hereby agrees to enter into this Corporate Integrity Agreement (the "Agreement" or "CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to enhance compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter referred to collectively as the "Federal health care programs") by Hospital, its employees, agents, and physicians with staff privileges. On or about this date, Hospital is entering into a settlement agreement with the United States and this CIA is incorporated by reference into that settlement agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by Hospital under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified).

III. CORPORATE INTEGRITY OBLIGATIONS

Hospital represents that it is currently a member of Jefferson Health System ("JHS"), a system of acute care hospitals, non-acute health care service providers and physician practices, with its corporate headquarters located in Radnor, PA. Hospital further represents that JHS currently has in place a Corporate Compliance Program and a Code of Conduct which apply to

Hospital as a member organization of JHS. As part of this CIA, Hospital agrees that the JHS Corporate Compliance Program and Code of Conduct shall remain in effect as to Hospital for three years from the date of execution of this CIA and that such Corporate Compliance Program includes the following features applicable to Hospital:

a. Compliance Officer. Hospital represents and agrees that, in accordance with the JHS Corporate Compliance Program, a Compliance Officer or Assistant Compliance Officer is responsible for developing, implementing, monitoring, revising, and reporting on compliance with policies and procedures and practices designed to further compliance with the requirements set forth in the JHS Corporate Compliance Program and Code of Conduct, and with the requirements of the Federal health care programs. The Compliance Officer or Assistant Compliance Officer shall continue to make regular reports regarding compliance matters directly to the Hospital CEO and/or to the Executive Committee of the Board of Trustees of JHS.

b. Code of Conduct. Hospital represents and agrees that, in accordance with the JHS Corporate Compliance Program, JHS has developed and effectively implemented a written Code of Conduct that applies to Hospital regarding compliance with federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. The Code of Conduct specifically requires that all claims submitted to any Federal health care program be properly supported by documentation by the treating physician in the patient's medical record. The Code of Conduct includes disciplinary guidelines and methods for employees to make complaints and notifications about compliance issues to Hospital management through the Confidential Disclosure Program described in section III(d). The Hospital also has underlying policies and procedures that specifically require that all inpatient claims intended to be submitted to Medicare with a principal diagnosis code of 482.89 (or any successor to this code) shall first be subject to pre-billing review to ensure that the diagnosis code

was properly assigned. The Code of Conduct has been distributed by Hospital to all employees and all individuals engaged by Hospital as independent contractors, and all other individuals affected by them, including but not limited to all personnel with responsibilities pertaining to coding and all physicians with privileges. Hospital shall review the Code of Conduct and underlying policies and procedures at least annually and shall update them as appropriate.

Within 120 days after the execution of this CIA, or within 30 days after the commencement of the individual's relationship with the hospital (e.g., employment or contract), whichever is later, and annually thereafter, each individual who should receive the Code of Conduct shall certify that he or she has read and understands the Code of Conduct. Hospital shall keep a copy of these certifications on file for at least one year after the completion of the corporate integrity period mandated by this CIA.

c. Training and Education. Hospital represents and agrees that, in accordance with the JHS Corporate Compliance Program, Hospital provides at least one hour of general education and training annually to: (1) all employees; and (2) all other individuals engaged by Hospital as independent contractors with responsibility for providing, documenting, or billing for services reimbursable by any Federal health care program (hereinafter collectively referred to as "covered individuals"). This general education and training: (1) covers the JHS Code of Conduct; (2) reinforces the need for strict compliance with the applicable statutes, regulations, policies, procedures, and program guidelines, and the JHS Code of Conduct; and (3) advises individuals that any failure to comply may result in disciplinary action. In accordance with the terms of this CIA, Hospital agrees to provide one hour of general training to covered individuals within 120 days of the effective date of this CIA and one hour annually thereafter. New covered individuals shall receive the general training described above within 90 days of the beginning of their employment or relationship with Hospital or within 120 days of the effective date of this CIA,

whichever is later. In addition to the general training described above, within 120 days of the effective date of this CIA each covered individual involved in the assignment of diagnosis or procedures codes for billing Federal health care programs shall receive 3 hours of specialized training regarding proper coding and billing and the applicable statutes, regulations, policies, procedures, and program guidelines for Federal health care programs. Persons providing the training must be knowledgeable about the subject area. New covered individuals with any responsibility for the preparation or submission of claims and/or the assignment of procedure codes shall receive this training within 30 days of the beginning of their employment or relationship with Hospital or within 120 days of the effective date of this CIA, whichever is later. Annually thereafter, Hospital shall require and provide three hours of the above described coding training to such individuals. If, after expiration of the 120 day period following execution of this CIA, a new covered individual has any responsibility for the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Hospital employee who has completed this specific training shall review all of the untrained person's work regarding the preparation or submission of claims and/or the assignment of procedure codes. Hospital represents and agrees that, in accordance with the JHS Corporate Compliance Program, Hospital shall make both the general and the specialized training described above available to all physicians with privileges, to the extent feasible, and shall encourage their attendance and participation. Hospital shall monitor the attendance of physicians at such training and shall maintain a record of the percentage of physicians with privileges who have attended such training. Each individual who is required to attend general and/or specialized training shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain

the certifications, along with specific course materials. These shall be made available to OIG upon request.

d. Confidential Disclosure Program. Hospital represents that, as part of the JHS Corporate Compliance Program, JHS has established a confidential disclosure program that encourages and permits employees and others to communicate about compliance issues to the Compliance Officer and agrees that it will maintain such program for the corporate integrity period. The JHS Corporate Compliance Program includes a toll-free telephone service, known as *ComplyLine*, and other means for employees and others to disclose any practices or procedures with respect to any Federal health care program, alleged by the individual to be inappropriate, to the Compliance Officer or some other person who is not in the reporting individual's chain of command. The JHS confidential disclosure program emphasizes a non-retribution, non-retaliation policy, and includes a reporting mechanism for anonymous, confidential communication. The JHS confidential disclosure program uses intake procedures designed to elicit all relevant information from individuals reporting alleged misconduct. For any report that is sufficiently specific that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides opportunity for the taking of corrective action, Hospital requires the internal review of the allegations set forth in such disclosure and ensures that proper follow-up is conducted. For each such report, Hospital, in good faith, makes a preliminary inquiry into the allegations set forth in every disclosure to ensure that it has obtained all of the information necessary to determine whether it should conduct an internal review as provided above. The Compliance Officer maintains a confidential disclosure log, which includes a record of each allegation received, status of the investigation of the allegation, and any corrective action taken in response to the investigation of a reported

allegation. The Compliance Officer maintains all documentation related to information in the log and shall make such documents available for inspection by the OIG upon request.

e. Review Procedures. Hospital's Internal Audit Department shall perform review procedures to assist Hospital and OIG in assessing the adequacy of its billing and compliance practices pursuant to this CIA. The reviews shall be done annually and cover each of the one-year periods beginning on the effective date of this CIA or the anniversary of that date. The Internal Audit Department shall use individuals who have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Hospital seeks reimbursement. The Internal Audit Department shall conduct an analysis of Hospital's billing to the Federal health care programs to assist Hospital and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). Hospital shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to review whether Hospital has performed the billing engagement in conformance with the agreed-upon procedures as described below. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Hospital seeks reimbursement. Hospital shall also engage the Independent Review Organization to conduct an engagement to determine whether Hospital is in compliance with this CIA ("compliance engagement"). Hospital shall require the Independent Review Organization to produce reports on its findings, which report shall be included in Hospital's Annual Reports to the OIG. The Independent Review Organization must be retained to perform these functions for the first year within 120 days of the effective date of this CIA. A complete copy of the Independent Review Organization's reports shall be included in each of Hospital's Annual Reports to OIG. After the submission of the first Annual Report,

the OIG, in its sole discretion, may exempt Hospital from the requirement to engage an Independent Review Organization for the second and third years of this Agreement.

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted to the Federal health care programs for the 12-month period covered by the engagement. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling. To generate the random sample, Hospital shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/oig/oas/ratstat.html."

Each annual billing engagement and its corresponding report shall include the following components:

- a. *Billing Engagement Objective:* a clear statement of the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. *Billing Engagement Population:* the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.

- c. Sources of Data: a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.
- d. Sampling Unit: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest.
- e. Sampling Frame: the identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement report shall provide:

- a. findings regarding Hospital's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);
- b. findings regarding whether Hospital is submitting accurate claims and cost reports for services billed to the Federal health care programs.
- c. findings regarding Hospital's procedures to correct inaccurate billings or codings to the Federal health care programs;
- d. findings regarding the accuracy of the coding hospital admissions involving a principal diagnosis of pneumonia; and
- e. findings regarding the steps Hospital is taking to bring its operations into compliance or to correct problems identified by the audit;

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement that shall provide findings regarding whether Hospital's program, policies, procedures, and operations comply with the terms of this CIA. This report of the engagement shall provide section by section findings regarding the requirements of this CIA.

3. *Verification/Validation.* In the event that OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which Hospital is complying with its obligations under this CIA, Hospital agrees to pay for the reasonable cost of any such review or engagement by OIG or any of its designated agents.

f. Reporting.

1. *Reporting of Overpayments.* If, at any time, Hospital identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, Hospital shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring.

2. *Reporting of Material Deficiencies.* If Hospital determines that there is a material deficiency, Hospital shall notify the OIG within 30 days of discovering the material deficiency. The report to the OIG shall include:

- a. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;
- b. Hospital's actions to correct the material deficiency (including all relevant information regarding the repayment of any overpayments related to the material deficiency); and
- c. any further steps Hospital plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and

payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" shall mean anything that has a significant, adverse financial impact upon the Federal health care programs, which may be the result of an isolated event or a series of occurrences, and which lacks conformity with Federal health care program reimbursement principles or other applicable statutes, and the regulations and written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents, or any other agency charged with administering the health care program implicated and/or its agents.

g. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* Hospital shall not hire or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Hospital shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.amet.gov/epl>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.dhhs.gov/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within ninety (90) days of the effective date of this CIA, Hospital will review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, Hospital will review the list at least semi-annually. If Hospital has notice that an employee, agent, or physician has become an Ineligible Person, Hospital will remove such person from responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Hospital has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with Hospital, within 10 days of receiving such notice Hospital will remove such individual from responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this CIA, OIG or its duly authorized representative(s) may examine any of Hospital's non-privileged books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) Hospital's compliance with the terms of this CIA; and (ii) Hospital's compliance with the requirements of the Medicare, Medicaid and other federal health care

programs. The documentation described above shall be made available by Hospital at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any Hospital employee who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG so long as such interview does not unreasonably interfere with the Hospital's operations. Hospital agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request. Hospital's employees may agree to be interviewed with or without a representative of Hospital present.

V. INITIAL AND ANNUAL REPORTS

Within 150 days after the execution of this CIA, Hospital shall submit a written report to the OIG. This initial report shall include: (1) a description of the training programs implemented pursuant to III(c) and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines from the training sessions. Thereafter, Hospital shall annually submit to the OIG a written report ("Annual Report") within 90 days after the first, second, and third anniversary dates of the execution of this CIA, with respect to the status and findings of Hospital's compliance activities. The Annual Reports shall include: (1) any change in the identity or position description of the Compliance Officer described in III(a); (2) any changes or amendments to the Code of Conduct or underlying policies and procedures required by III(b); (3) a description of any changes in the training programs implemented pursuant to III(c) and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines for the training sessions and a report of the percentage of physicians with staff privileges who have attended training; (4) a description of:

(a) the audits conducted pursuant to III(e); (b) the results of such audits; (c) the problems identified in the audits; and (d) the corrective actions taken to address those problems; (5) a description of the reports received and actions taken by Hospital pursuant to III(d) and a copy of the confidential disclosure log required by that section; (6) a description of any personnel action taken by Hospital as a result of the obligations in section III(g); (7) a description of any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Hospital has committed a crime or has engaged in fraudulent activities; (8) a certification by the Compliance Officer that, other than as disclosed in the Annual Report or as otherwise disclosed to HHS-OIG pursuant to the CIA, to the best of his/her knowledge and belief, Hospital is in compliance with the terms of this CIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this CIA, all notifications and reports required under the terms of this CIA shall be submitted to the entities listed below:

If to the OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Phone: 202-619-2078
Fax: 202-205-0604

If to Hospital:

Dorothy O. McGilvery
Corporate Compliance Officer
Jefferson Health System
259 Radnor - Chester Road
Suite 290
Radnor, PA 19087-5261
Phone: 610-225-6232
Fax: 610-225-6260

VII. DOCUMENT AND RECORD RETENTION

Hospital shall maintain for inspection documents and records relating to this CIA until the fourth anniversary of the execution of this CIA or longer if otherwise required.

VII. BREACH AND DEFAULT PROVISIONS

Hospital is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to. Nothing in this CIA affects the rights of the OIG or the United States to exercise any criminal, civil, or administrative authority with respect to conduct of Hospital or others.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Hospital and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days after the effective date of this CIA and concluding at the end of the term of this CIA, Hospital fails to have in place any of the following:

- a. a Compliance Officer;
- b. a Compliance Committee;

- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a training program; and
- f. a Confidential Disclosure Program;

2. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Hospital fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to OIG.

3. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day Hospital:

a. hires or enters into a contract with or grants staff privileges to an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which Hospital can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III(g)) as to the status of the person);

b. employs, contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which Hospital can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III(g)) as to the status of the person); or

c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Hospital's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after Hospital received notice of the relevant matter or after the resolution of the matter).

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the Hospital fails to grant access) for each day Hospital fails to grant access to the information or documentation as required in section IV of this CIA.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue 10 days after the date that OIG provides notice to Hospital of the failure to comply) for each day Hospital fails to comply fully and adequately with any obligation of this CIA. In its notice to Hospital, OIG shall state the specific grounds for its determination that the Hospital has failed to comply fully and adequately with the CIA obligation(s) at issue. With respect to the Stipulated Penalty provision described in this section VIII.A.5 only, the OIG shall not seek a Stipulated Penalty if Hospital demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) Hospital has begun to take action to cure the failure to comply, (ii) Hospital is pursuing such action with due diligence, and (iii) Hospital has provided to OIG a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Hospital has failed to comply with any of the obligations described in section VIII.A and determining that Stipulated Penalties are appropriate, OIG shall notify Hospital by personal service or certified mail of (a) Hospital's

failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within fifteen (15) days of the date of the Demand Letter, Hospital shall either (a) cure the breach to OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section VIII.D. In the event Hospital elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Hospital cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section VIII.C.

3. *Timely Written Requests for Extensions.* Hospital may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Hospital fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after Hospital receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

4. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

5. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's determination that Hospital has materially breached this CIA, which decision shall be made at OIG's discretion and governed by the provisions in section VIII.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Hospital constitutes an independent basis for Hospital's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Hospital has materially breached this CIA and that exclusion should be imposed, OIG shall notify Hospital by personal service or certified mail of (a) Hospital's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude Letter").

2. *Opportunity to Cure.* Hospital shall have 35 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to OIG's satisfaction that:

- a. Hospital is in full compliance with this CIA;
- b. the alleged material breach has been cured; or
- c. the alleged material breach could not be cured within the 35-day period, but that: (i) Hospital has begun to take action to cure the material breach, (ii) Hospital is pursuing such action with due

diligence, and (iii) Hospital has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the 35-day period, Hospital fails to satisfy the requirements of section VIII.C.2, OIG may exclude Hospital from participation in the Federal health care programs. OIG will notify Hospital in writing of its determination to exclude Hospital (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section VIII.D; below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Hospital is excluded under the provisions of this CIA, Hospital may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this CIA means:

- a. a failure by Hospital to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III(f)
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section VIII.A of this CIA;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section VIII.B above; or
- d. a failure to perform the audits in accordance with section III(e).

D. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Hospital of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Hospital shall be afforded certain review rights comparable to

the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving stipulated penalties shall be made within 15 days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 30 days of the date of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be (a) whether Hospital was in full and timely compliance with the obligations of this CIA for which OIG demands payment; (b) the period of noncompliance and (c) with respect to a stipulated penalty authorized under section VIII.A.5 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) Hospital had begun to take action to cure the failure to comply, (ii) Hospital was and is pursuing such action with due diligence, and (iii) Hospital had provided to OIG a reasonable timetable for curing the material breach which is being followed. Hospital shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for OIG with regard to a finding of a breach of this CIA and orders Hospital to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision notwithstanding that Hospital may request review of the ALJ decision by the DAB.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for

exclusion based on a material breach of this CIA shall be (a) whether Hospital was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not be cured within the 35-day period, but that by the end of that period (i) Hospital had begun to take action to cure the material breach, (ii) Hospital was and is pursuing such action with due diligence, and (iii) Hospital had provided to OIG a reasonable timetable for curing the material breach which is being followed. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to OIG. Hospital's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Hospital upon the issuance of the ALJ's decision. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 30 days after the ALJ issues such a decision, notwithstanding that Hospital may request review of the ALJ decision by the DAB.

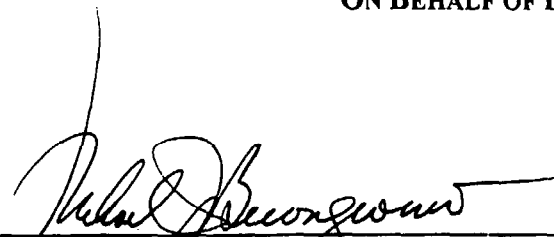
IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Hospital and the OIG agree as follows:


1. this CIA shall be binding on the successors, assigns and transferees of Hospital;
2. this CIA shall become final, binding, and effective upon the settlement agreement into which this CIA is incorporated becoming effective;
3. any modifications to this CIA shall be made with the prior written consent of the parties of this CIA; and
4. the undersigned Hospital signatories represent and warrant that they are authorized to execute this CIA. The undersigned United States signatory

represents that he is signing this CIA in his official capacity and that he is
authorized to execute this CIA.

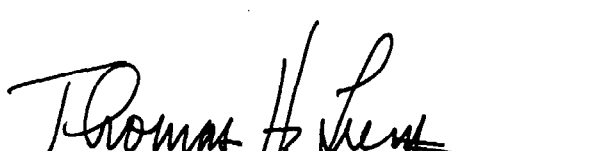
ON BEHALF OF LANKENAU HOSPITAL


MICHAEL J. BUONGIORNO
Vice President, Finance and Treasurer
Main Line Health, Inc.,

12/14/99
DATE


BARRY RABNER
Senior Vice President
Main Line Health, Inc.

12/16/99
DATE


THOMAS H. LEE, II
Dechert Price & Rhoads
Counsel to Lankenau Hospital

12/17/99
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Officer of Inspector General
U.S. Department of Health and Human Services

12/14/95
DATE